PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2008/000309	06.03.2008	07.03.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/053 A61B5/029
ADD. A61B5/00

Applicant
CHEETAH MEDICAL LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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Date of completion of this opinion
see form PCT/ISA/210

Authorized Officer

Görlach, Tobias

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 1-11

because:

☒ the said international application, or the said claims Nos. 1-11 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 1-11

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	12-26
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	12-26
Industrial applicability (IA)	Yes:	Claims	12-26
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III
Non-establishment of opinion

1. Claims 1-11 relate to methods which comprise the steps of

(i) performing measurements on a human or animal body
(ii) comparing these measurements to standard values
(iii) detecting a deviation from these standard values
(iv) associating this deviation from standard values with a clinical picture.

The methods of claims 1-11 therefore have to be considered as diagnostic methods in the sense of Rule 39.1(iv) PCT, for which no search is required. For the same reason, these claims do not have to be examined (Article 34(4)(a)(i) and Rule 67.1(iv) PCT).

Claims 22-26 have only been examined insofar as they relate to an apparatus or a system.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1992, STOOHS R ET AL: "CARDIOVASCULAR CHANGES ASSOCIATED WITH OBSTRUCTIVE SLEEP APNEA SYNDROME" XP002488467 Database accession no. PREV199293105800

D2: WO 2006/087696 A (NEW LEAF CAPITAL LTD [GB]; KEREN HANAN [IL]; SIMON AVRAM B [GB]) 24 August 2006 (2006-08-24) cited in the application

D3: RAZA S B ET AL: "FILTERING RESPIRATION AND LOW-FREQUENCY MOVEMENT ARTEFACTS FROM THE CARDIOGENIC ELECTRICAL IMPEDANCE SIGNAL" MEDICAL AND BIOLOGICAL ENGINEERING AND COMPUTING, SPRINGER, HEILDELBERG, DE, vol. 30, no. 5, 1 September 1992 (1992-09-01), pages 556-561, XP000323425 ISSN: 0140-0118

D4: DATABASE EMBASE [Online] ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL; May 1994 (1994-05), SCHUMACKER P T ET AL: "Oxygen delivery and uptake relationships in patients with aortic stenosis" XP002488468 Database accession no. EMB-1994152503

D5: US 2005/217674 A1 (BURTON DAVID [AU] ET AL) 6 October 2005 (2005-10-06)

2. The present application does not meet the criteria of the PCT, because the subject-matter of claims 12 and 13 does not involve an inventive step in the sense of Article 33(3) PCT.

2.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 12, and discloses (the references in parentheses applying to this document):

> Apparatus for monitoring sleep of a sleeping subject using output radiofrequency signals transmitted to the subject during sleep and input radiofrequency signals received from the subject during sleep (abstract), the apparatus comprising:
> a sleep apnea identification unit configured for identifying sleep apnea events based on said cardiac output (abstract).

(it may be noted that the connection between cardiac output, also determined by bioimpedance measurements, and sleep apnea is also disclosed in other articles and abstracts cited in the search report).

2.2 The subject-matter of claim 12 therefore differs from this known sleep monitoring apparatus in that a phase shift between applied and measured signals is used to determine cardiac output.

The problem to be solved by the present invention may therefore be regarded as providing an alternative way of measuring cardiac output.

However, these features have already been employed for the same purpose in a similar cardiac output measuring device, see document D2, page 19, line 22 - page 20, line 18. It

would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a sleep monitoring device according to document D1, thereby arriving at a device according to claim 12.

Therefore, the solution proposed in claim 12 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

The additional features of claim 13 are disclosed in document D2 as follows:

> A system comprising:
> a radiofrequency generator (22) for generating output radiofrequency signals;
> a plurality of electrodes (25) designed for transmitting said output radiofrequency signals (24) to the subject (21) and for sensing input radiofrequency signals (26) from the subject.

The subject-matter of claim 13 therefore does not involve an inventive step either (Article 33(3) PCT). See also the remarks under Item VIII, point 1.

3. Dependent claims 14-26 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step:

- Claim 14: see abstract of D1.
- Claims 15 and 16: see abstract of D4 (for claim 15, see also Item VIII, point 2).
- Claims 17 and 18: see document D5, paragraphs 53 and 54 (for claim 17, see also Item VIII, point 3).
- Claim 19: see document D2, page 20, line 19 - page 21, line 2.
- Claim 20: see document D2, page 21, lines 10-30.
- Claims 21-24: see document D3, page 557, left column, paragraph 3, and page 558, right column, first paragraph.
- The cut-off frequencies given in claims 25 and 26 appear to relate to arbitrary choices for these frequencies.

Re Item VIII

Certain observations on the international application

1. Claim 13 is drafted as an independent claim. However, this claim contains all the features of claim 12. In order to fulfil the requirements of Article 6 PCT with respect to conciseness, claim 13 should be drafted as a dependent claim, particularly because "apparatus" and "system" relate to the same claim category (PCT Guidelines, 5.13).

2. Claim 15 relates to a "total oxygen delivery estimator". It is however not clear from this claim how the total oxygen delivery is estimated (e.g. what parameters are used for the estimate, which is only disclosed in the description). Also, claim 15 depends on claim 13, whose subject-matter does not comprise an oxygen measuring device. Hence, claim 15 does not fulfil the requirements of Article 6 PCT with respect to clarity.

3. Claim 17 refers to a therapy device; however, this device is not claimed in claim 17 (cf. claim 18). This makes the exact scope of claim 17 unclear (PCT Guidelines, 5.37). Furthermore, claim 17 is drafted as a claim dependent on claim 13, but refers to total oxygen delivery, which is mentioned in claims 15 and 16 rather than in claim 13. Therefore, claim 17 does not fulfil the requirements of Article 6 PCT with respect to clarity.